APPENDIX L

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

Amgen Manufacturing, Limited; Immunex Rhode Island Corporation; and Amgen USA Inc., **Plaintiffs,** **vs.** **The Trustees of Columbia University in the City of New York, a New York corporation,** **Defendant.**	**NO. 04-12626 MLW** **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS**

Plaintiffs, Amgen Manufacturing, Limited, Amgen USA Inc. and Immunex Rhode Island Corporation (collectively, "Plaintiffs" or "Amgen Affiliates") have properly alleged the existence of a case or controversy. As demonstrated below, Columbia's Motion to Dismiss for lack of declaratory judgment jurisdiction – which ignores controlling law and critical facts – lacks merit and should be denied.

Columbia's motion is the latest in a long series of tactics designed to manipulate proceedings in the U.S. Patent and Trademark Office ("PTO") and then in the courts, to delay the determination that the public is entitled to use any invention that was the subject of the Axel patents. Columbia's assertion that it does not intend to sue the Affiliates "right now" (Columbia Memo., p. 2) misses the mark; it is precisely because Columbia does not want to sue the

Affiliates "right now" but insists on the right to sue them *later* for things they are *doing* "right now" that the Affiliates need a declaration.

Last year, Columbia moved to stay the determination of the validity of the '275 patent because its claims may change in re-examination. Columbia rehashes that argument now, saying that it may not be necessary to litigate the '275 patent "as it now reads." Columbia Memo, p. 2. But this Court has already rejected Columbia's argument that it should defer judicial action because "the PTO proceedings might moot, limit or alter the issues presented to the Court" as "not persuasive." Order, Aug. 16, 2004, p. 5. As the Court then noted:

> A stay would significantly harm the plaintiffs. While any stay is in effect, the drug companies' potential damages will mount. The uncertainty over whether they owe Columbia royalties on their products might create difficulties in pricing those products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent. Such efforts are likely to be extremely costly in a highly regulated industry such as the one in which the drug companies compete because changes in their product designs or manufacturing processes may require regulatory approval.
>
> Eliminating this uncertainty is the very reason that the plaintiffs brought these declaratory judgment actions. It is also the reason that Congress and the President created a declaratory judgment remedy.

Order, Aug. 16, 2004, pp. 8-9. Amgen's Affiliates face that same uncertainty.

Columbia never disputed that there was a case or controversy between it and Amgen Inc. and Immunex Corporation (collectively "Amgen") regarding the '275 patent until it filed its Covenant Not To Sue (the "Covenant"). The Covenant to Amgen, however, is made illusory as a practical matter -- and Columbia would achieve the same effect as from the stay that the Court denied -- by Columbia's failure to extend the Covenant to the Amgen Affiliates involved in the exact *same* accused activity. Unless the Court sees through Columbia's gambit, Columbia will have achieved exactly the result it sought by its stay motion -- deferral of any decision on the

merits, while reserving its claim for damages as to current and ongoing activities of the Amgen group of companies.

Ultimately, Columbia rests its motion on its repeated but inaccurate denial that it has ever alleged "'that [Amgen's] activities are covered by one or more claims of the '275 patent'" (Columbia Memo., p. 8) and later again the denial that it has asserted "that Amgen's activities are covered by one or more claims of the '275 patent" *Id.* at p. 9 n.5.[1] That assertion is untenable, given the allegations in Columbia's February 12, 2004 Answer and Counterclaims in the *Amgen* action that "Columbia admits that its license agreements with Amgen and Immunex obligate Amgen and Immunex to pay royalties *based upon, inter alia, the '275 patent*, and that Columbia has so advised Amgen and Immunex" (Columbia's Answer and Counterclaims, p. 3, ¶ 5 (emphasis added)),[2] and that "Amgen has breached . . . the License Agreement by, *inter alia*, failing to pay royalties on sales of licensed products." *Id.* at p. 23, ¶ 14. The major dispute between Amgen and Columbia in the MDL proceeding has always concerned Columbia's claim that the '275 patent covers Amgen's activities – a claim that changed from a royalty claim to an infringement claim when Columbia then purported to terminate its license. When Columbia told this Court on June 22, 2004, that it intended to sue for infringement, that could only have been a reference to the '275 patent. Columbia's suggestion of convenience now, that it has never asserted that the '275 patent claims cover the activities of Amgen, lacks any credibility.

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[1] Columbia also argues that it never made any "assertion that Amgen's activities would infringe the '275 patent in the absence of a license" (Columbia Memo., p. 8) and again denies "any allegation that any activities of Amgen or Immunex are 'covered' by any patent at all, let alone the '275 patent." *Id.* at pp. 8-9. *See also* Columbia's subjunctive hypothetical: "even if Columbia had asserted that Amgen had a royalty obligation under the '275 patent." *Id.* at p. 7.

[2] A copy of the Columbia Answer and Counterclaims is attached hereto as Exhibit A. Under the License Agreement, Amgen would only be obligated to pay royalties based upon the claims of the '275 patent if Amgen's products were "covered by a claim" of that patent. *See* Compl., Ex. D (License Agreement), Section 1(c)(i).

STATEMENT OF FACTS

I. Columbia obtained the '275 patent by delay and manipulation of the patent process

Columbia secured four patents, the '216, '665, '017 and '275 patents (collectively, "the Axel Patents") from the PTO, all based on the same patent application filed February 25, 1980. Compl., ¶ 2. The first Axel patent issued in 1983 (the '216 patent). However, Columbia continued to prosecute its application to obtain further patents on the same alleged invention. Faced with a double patenting rejection on August 12, 1985, Columbia filed a terminal disclaimer in order to get its second Axel patent (the '665 patent). Faced with another double patenting rejection on January 8, 1992, Columbia filed a terminal disclaimer in order to get its third Axel patent (the '017 patent). Thus, by 1993, Columbia had three Axel patents (collectively, "the prior issued Axel patents") all of which would expire on August 16, 2000.

Columbia then tried a new set of tactics to delay and elude the oversight of the PTO while trying to get yet another 17 year patent term on the same invention. For example, as detailed in the Complaint (¶¶ 64-69), when one examiner rejected Columbia's further application in February, 1998 by reason of its duplication of the purported invention described in the '017 patent, Columbia cancelled the pertinent transformed cell claim, then maneuvered in other directions for years, and when a new examiner was in place in 2001 it added claims like that cancelled in 1998 but did not advise the new examiner about the 1998 rejection. As to other such tactics, *see generally* Complaint, ¶¶ 32-74. By such manipulation of the system, and by engaging in unreasonable and unexplained delay in its prosecution, Columbia managed to obtain a fourth Axel patent (the '275 patent) in September, 2002.

II. Columbia engaged in demands based on the '275 patent, but has used tactics of evasion and delay to avoid the determination of its validity

After the prior issued Axel patents expired on August 16, 2000, Columbia demanded that Amgen continue to pay royalties because Columbia had additional pending patent applications claiming priority to the 1980 patent application, one of which later matured into the '275 patent. *Id.* at ¶ 3. Amgen filed suit in June, 2003 to challenge this demand, and on March 9, 2004, Columbia abandoned its claim to be owed royalties based on pending patent applications. However, on that same date Columbia also purported to terminate the Amgen license,[3] and Columbia did not abandon its Answer and Counterclaims filed February 12, 2004, in which it asserted that Amgen owed royalties *based on the '275 patent* and accordingly claimed royalties from Amgen.

When Columbia was later faced with the prospect that the validity of the '275 patent would be determined in an adversarial judicial proceeding in this Court, Columbia tried another avoidance tactic: it announced that it would file a Reissue Application in the PTO regarding that patent, and moved to stay the court proceedings. The Court denied Columbia's motion to stay, and scheduled the double patenting issue for discovery and determination before the end of the year. Columbia never suggested that its assertions regarding the '275 patent did not raise a justiciable case or controversy between it and Amgen, and indeed the Court recognized the need of Amgen and the other plaintiffs to have a determination regarding the patents:

> While any stay is in effect, the drug company's potential damages will mount with uncertainty over whether they owe Columbia royalties on its products. It may create difficulty in pricing those products. It may cause the delay of introduction of new products or needlessly invest money in efforts to design around the invalid patent.

Hearing Transcript, June 22, 2004, at 40:18-24.

As a result of the denial of the stay, upcoming expert and fact witness discovery threatened to lay bare the manipulation Columbia had practiced on the PTO. And Columbia

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[3] Until Columbia purported to terminate the Amgen license, Plaintiffs were protected by it and had no reason to sue Columbia.

knew that it would need to disclose such evidence to the PTO in the reissue proceeding. As its next avoidance tactic, on September 2, 2004, Columbia filed an "Emergency Motion" to dismiss, supported by a Covenant. That Covenant was riddled with exceptions and limitations, designed to give a minimum of assurance to the plaintiffs while arguably supporting a dismissal (and thus further delay) of actions to establish the invalidity of the patent.

In ensuing hearing before the Court on October 6, and because Columbia's Covenant was inadequate to negate a case or controversy as to Amgen and other plaintiffs, Columbia extended the Covenant to be permanent. This Court ruled on November 5, 2004, that the extended Covenant was satisfactory to support dismissal of the patent counts as to Amgen. *In re Columbia Univ. Patent Litig.*, 343 F. Supp. 2d 35 (D. Mass. 2004).

However, Columbia explicitly refused to extend the Covenant to Amgen's Affiliates – the Plaintiffs herein – on the ground that they were not parties to the action and thus no issue was before the Court as to them. Because these Plaintiffs are actually and regularly engaged in the exact conduct that Columbia told Amgen was covered by the '275 patent claims, they present the same case or controversy that existed as to Amgen before Columbia granted its Covenant. Any value of the Covenant for Amgen's operations is undermined *completely* by Columbia's failure to extend the Covenant to members of the Amgen group that participate in the accused activities. Accordingly, in this action Plaintiffs seek a judicial declaration that the '275 patent is invalid, unenforceable and/or is not being infringed by Plaintiffs, and that Columbia's purported termination of Plaintiffs' license rights was invalid.

III. Columbia's actions demonstrate its intent to enforce the '275 patent against Plaintiffs, though at a time and in a court of Columbia's choosing

As alleged at paragraph 75 of the Complaint, Columbia has engaged in a lengthy and sustained course of conduct demonstrating its intention to enforce the '275 patent against Plaintiffs.[4]

Columbia has demanded that Amgen pay royalties under the License Agreement because of the '275 patent, both in correspondence leading to Amgen's action (*see* Compl., ¶ 75(e))[5] and, more formally, by alleging in its Answer and Counterclaims that "Columbia admits that its license agreements with Amgen and Immunex obligate Amgen and Immunex to pay royalties *based upon, inter alia, the '275 patent*, and that Columbia has so advised Amgen and Immunex." Columbia's Answer and Counterclaims, p. 3, ¶ 5 (emphasis added). In the same filing, Columbia alleged accordingly that "Amgen has breached . . . the License Agreement by, *inter alia*, failing to pay royalties on sales of licensed products." *Id.* at p. 23, ¶ 14. When Amgen did not pay, Columbia then purported to terminate the license agreement between Columbia and Amgen, thus purporting to terminate Plaintiffs' rights as affiliates of Amgen and converting the

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[4] Columbia licensed the Axel patents to Amgen "and its Affiliates." Compl., Ex. D, § 2(a). Accordingly, when Columbia purported to terminate the License Agreement with Amgen, it also purported to terminate Plaintiffs' license rights as Amgen Affiliates. *Id.* at ¶ 72(g).

[5] Columbia's outside counsel's letter of November 12, 2002 to Immunex (copy attached as Exhibit B), for example, had two enclosures (a copy of the '275 patent, and a copy of a case where Columbia had sued to enforce an expired Axel patent), and adverted to being "forced to consider alternative approaches to addressing the failure of Immunex to comply with its obligations" – a thinly veiled threat of litigation. Although Columbia's motion complains that Amgen's Complaint referencing this language is "hopelessly vague," and that Columbia's threat letter did not specify what "alternative approaches" it might have meant (Columbia Memo., p. 8), courts are smart enough to understand the innuendo. *See, e.g., Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 272 (D. Md. 1998) (motion for summary judgment denied where patentee had publicly stated its policy to use patent infringement

accusation of breach to an accusation of infringement. The essence of a license agreement is a promise not to sue. There was no purpose to termination of this License Agreement except to clear a path to sue for infringement.

Columbia then announced its *intention* to sue for infringement. At the hearing on June 22, 2004, Columbia's counsel stated:

> Here's what I mean. If the case were simply to go forward without staging, we would likely be filing infringement counterclaims. They would have their validity defenses.

Hearing Transcript, June 22, 2004, p. 54. And again:

> . . . we have counterclaims that we would like to assert, both breach of contract, which will live no matter what, and infringement, but won't be done now, but I think we should at least –
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> THE COURT: Why?
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> MR. GINDLER: Because I think that it's only fair to just close the pleadings and to put our claims on the table, and the infringement claims could be terminated if we lose on double patenting.

Id. at 194-95.[6] (At the Court's suggestion, Columbia agreed that it could wait until January 2005 to plead its infringement counterclaims. *Id.* at 196-97.)[7]

To circumvent this Court's denial of a stay, Columbia granted a Covenant to Amgen but not to the Affiliates *for their participation in the same activity* – thus helping itself to the stay the

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litigation against generic competitors, and had made "statements – pregnant with ominousness – that it had no basis for determining whether Pharmadyne was infringing the '431 patent.")

[6] This echoed Columbia's comments at the MDL hearing: "[W]ill there be claims by Columbia back against the biotech companies for infringement or for breach of contract? And the answer is, probably." Hearing Transcript, March 23, 2004, p. 4, attached hereto as Exhibit C.

[7] Columbia further errs now in arguing that "an infringement action . . ., unlike a suit to enforce a contractual royalty obligation, . . . puts the validity of the patent in question." Columbia Memo., pp. 7-8 n. 4. The invalidity of the '275 patent constituted a defense to Columbia's royalty claims. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 673-74 (1969).

Court had denied, while preserving its right to recover from the Amgen group of companies for the same conduct.

ARGUMENT

I. Plaintiffs have a reasonable apprehension that they will be sued for infringement of the '275 patent

The Federal Circuit has adopted a two-part test to determine whether a case or controversy exists that will sustain a declaratory judgment action in a patent case:

> First, the defendant's conduct must have created on the part of plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the device or have prepared to produce the device.

Arrowhead Industrial Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 736 (Fed. Cir. 1988) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987). The second of these requirements is present here, as Plaintiffs allege (Compl., ¶¶ 11-13) and as Columbia concedes in its motion. Columbia Memo., p. 4. Columbia's motion depends on its assertion that the requisite "reasonable apprehension" is not present.

Reasonable apprehension of an infringement suit exists under either of two circumstances – both of which are present here. First, a reasonable apprehension exists if a patentee threatens to bring suit or charges that the activity of a plaintiff is an infringement. *See Arrowhead Industrial Water, Inc.*, 846 F.2d at 736 ("If defendant has expressly charged a current activity of the plaintiff as an infringement, there is clearly an actual controversy, certainty has rendered apprehension irrelevant, and one need say no more."). Second, even in the absence of an express charge regarding infringing activity, "reasonable apprehension" can be shown by less direct conduct of the patentee. *See Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) ("Although the best evidence of a reasonable apprehension of suit comes in the form

of an express threat of litigation, an express threat is not required"); *Goodyear Tire & Rubber Co.*, 824 F.2d at 956 ("[W]e cannot read the Declaratory Judgment Act so narrowly as to require that a party actually be confronted with an *express* threat of litigation to meet the requirements of an actual case or controversy" (emphasis in original)). Rather, if the patentee has not threatened to bring an infringement suit or charged infringement, the court must consider the totality of the circumstances to determine if a reasonable apprehension of suit exists. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed. Cir. 1992) (holding that, in the absence of a charge of infringement "we must look . . . to the totality of the circumstances" (internal quotation omitted)).

A. Columbia has expressly charged that the *activity* of Plaintiffs is covered by the '275 patent

Columbia notes that this Court has observed that "Columbia has not, however, implicitly or explicitly threatened to sue *those entities* [the Affiliates]." *In re Columbia Univ. Patent Litig.*, 343 F. Supp. 2d at 42 (emphasis added)). But that is not the same thing as saying that Columbia has not accused *the activity* of the Plaintiffs. Columbia expressly asserted that Amgen's *activity* is covered by one or more claims of the '275 patent, and has purported to terminate Amgen's license and then announced its intention to counterclaim for infringement. This amounts to an accusation that these *activities* (in which the Amgen Affiliates are also engaged) are infringing the '275 patent.

Plaintiffs' apprehension that Columbia will bring suit against them for infringing the '275 patent is based on Columbia's previous litigation against Amgen regarding the *exact same activity*. Litigation with third parties regarding the same technology may give rise to a person's reasonable apprehension of suit. In *Teva Pharmaceuticals USA, Inc. v. Abbott Laboratories*, 301

F. Supp. 2d 819 (N.D. Ill. 2004), Abbott had filed in Canada a challenge to Teva's Canadian affiliate's marketing of generic BLAXIN; this, combined with Abbott's history of litigating against Teva in the U.S. as to some other drugs, was held to establish Teva's reasonable apprehension that Abbott would file a U.S. suit against Teva regarding BLAXIN. Lawsuits against *suppliers*, or *unrelated* manufacturers of *similar* products, may form a basis for apprehension of a suit against the declaratory plaintiff. *See C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 881 n.6 (Fed. Cir. 1983) (citing *Medtronic, Inc. v. American Optical Corp.*, 327 F.Supp. 1327, 1333 (D. Minn. 1971) (holding that "[i]n view of these statements, *and in view of the defendant's practice of threatening suit and actually bringing suit against alleged infringers of the related '990 patent,* the plaintiff could reasonably fear that the defendant would eventually sue it for infringement of the '428 patent.") (emphasis added)); *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 1991 WL 267892, at *5 (D. N.J. 1991) (suit by patentee against plaintiff's intended supplier of new product, plus past litigation of same patent against a different product of plaintiff's, sufficed for a reasonable apprehension of suit against the new product). Columbia's recital of the fact that it did not communicate directly *with Plaintiffs* (Columbia Memo., pp. 1, 5) overlooks the legal principle that "a reasonable apprehension may be found in the absence of *any* communication from defendant to plaintiff." *Arrowhead Industrial Water, Inc.*, 846 F.2d at 736 (emphasis in original); *see also FIGI Graphics, Inc. v. Estate of Edwards*, 1997 WL 567792, at *3 (D. Kan. 1997) (same). In addition, it simply begs credibility to assert that communications to Amgen would not also be communications to Amgen's affiliates, the Plaintiffs here.

B. The "totality of the circumstances" also show that Plaintiffs have a reasonable apprehension that Columbia will sue them, though at a time and place of its choosing

Commencing in September of 2002, Columbia engaged in a consistent course of conduct demonstrating its intent to enforce the '275 patent against licensed parties, including Amgen. Compl., ¶ 72. Courts recognize that "the fact that [the patentee] has already initiated suit against a company that engages in activities very similar to those of [the plaintiff] is relevant" to the case or controversy issue (*Ion Beam Applications, S.A. v. The Titan Corp.*, 156 F. Supp. 2d 552, 557 (E.D. Va. 2000)), and here the conduct of Amgen and of Plaintiffs is the *same* activity. *See also Cable/Home Communications Corp. v. Oak Industries, Inc.*, 1986 U.S. Dist. LEXIS 16544, at *3-4 (E.D. Pa. 1986) (case or controversy present where patentee had brought suit against seven others in industry, including the former corporate parent of the plaintiff which had conducted "the very business operation now conducted" by the plaintiff).

Columbia *never* contested that Amgen had a reasonable apprehension of suit in its case against Columbia until Columbia filed its Covenant, and indeed Columbia itself counterclaimed for declaratory relief and stated its intention in Court to counterclaim for infringement. In this case, Plaintiffs stand in the same position that Amgen occupied before that Covenant was issued. Columbia has not only refused to extend its Covenant to cover Plaintiffs, but also specifically amended the original version of the Covenant to clarify that it *excludes* affiliates such as Plaintiffs.[8] Moreover, in the final version of the Covenant, Columbia "categorically reject[ed]"

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[8] *Compare* Exhibit D attached hereto, Columbia's Covenant Not to Sue Plaintiffs for Infringement of the '275 Patent as It Presently Reads for Products Made, Used or Sold On or Before the Date of This Covenant (not discussing application to affiliates) *with* Exhibit E attached hereto, Columbia University's Amended and Restated Covenant Not to Sue Plaintiffs

any claim that the '275 patent is invalid, unenforceable or not being infringed by Amgen or its affiliates. Am. Covenant at 2. Taken together, these actions indicate Columbia's intent to enforce the '275 patent against any potential infringer, including Plaintiffs, but at a time and in a court of its choosing.

Even in less closely connected disputes than those in the MDL proceeding and here, the refusal of the patentee to give a covenant not to sue is a relevant factor to the plaintiff's reasonable apprehension. In *Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 242 F. Supp. 2d 311 (S.D.N.Y. 2003), the court held that a previous suit by defendant against plaintiff on *different patents*, a press release showing general intention of defendant to enforce patent rights, and the refusal of defendant to give a covenant not to sue, were sufficient circumstances to establish a reasonable apprehension. In the case at bar, there was a previous suit by defendant against Plaintiff's affiliates claiming coverage of their activity under the *same* patent, extensive efforts by defendant to enforce the *same* patent rights, and an explicit refusal in open court to extend the covenant to these Plaintiffs.[9]

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for Infringement of the '275 Patent ("Am. Covenant"), at 2 ("this covenant does not extend to any affiliate or customer of any plaintiff").

[9] As recognized even in one of Columbia's cited cases, "a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination" of reasonable apprehension. *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993). This case is unlike the situations in other cases cited by Columbia.

In *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed. Cir. 1992), the potential infringer was the one who approached the patentee and tried to provoke a dispute by eliciting "responses, characterizations and arguments" from discussions it initiated. *See also International Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1213 (7th Cir. 1980) (patentee not required to respond to request for clearance); *CAE Screenplates, Inc. v. Beloit Corp.*, 957 F. Supp. 784, 790 (E.D. Va. 1997) (same). Columbia started this dispute by claiming that the Amgen activities were covered by its patent, demanding royalties, then purportedly terminating the license and threatening infringement counterclaims. In that context, its refusal to extend the Covenant to Amgen affiliates loudly proclaims its eventual intentions.

Similarly, Columbia's reliance on *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 2003 WL 22888848 (D. Mass. 2003) is misplaced, where the patentee had not accused or taken actions

Columbia asserts that Plaintiffs have a "burden of proving that they have an objectively reasonable apprehension that Columbia is poised to bring an infringement suit." Columbia Memo., p. 14. That is not the law, and Columbia is contradicted by its own cited authority, *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d at 1054 ("a reasonable apprehension of suit does *not* require that the patentee be known to be poised on the courthouse steps") (emphasis added).

Repeatedly, Columbia argues for dismissal because Plaintiffs do not have a reasonable apprehension that Columbia will bring suit *for now*: not "right now" (Columbia Memo., p. 2); not "now" (*id.* at p. 10); not "imminent" (*id.*); not "tomorrow or the next day" or "right now" (*id.* at p. 11); Columbia is not "poised to bring an infringement action" (*id.*). Columbia is mistaken in arguing that its lack of desire to sue *at this moment*, or *until* the PTO has ruled on the reissue application, negates a current controversy.

> When the patentee takes steps that create a reasonable apprehension that he will seek redress through the courts, the alleged infringer is not required to wait for the patentee to decide when and where to sue, but can take the initiative and seek declaratory relief.

EMC Corp. v. Norand Corp., 89 F.3d 807, 811 (Fed. Cir. 1996), cited by Columbia; *see also Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1255 (Fed. Cir. 2002) (holding that "a patentee's present intentions do not control whether a case or controversy exists"); *Medtronic, Inc. v. American Optical Corp.*, 327 F.Supp. at 1333 (reasonable "fear that the defendant would *eventually* sue") (emphasis added).

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directed at the activity of the plaintiff. And in *Hewlett-Packard Co. v. Genrad, Inc.*, 882 F. Supp. 1141, 1156 (D. Mass. 1995) the patentee's oral threat of "dire consequences" was undercut by later written reassurances not to charge infringement as to existing products. Much more is present in this action than statements made in licensing negotiations or general comment about having a "strong proprietary position" as in *Cygnus Therapeutics Systems v. Alza Corp.*, 92 F.3d 1153 (Fed. Cir. 1996), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998), on which Columbia relies.

The facts of *Vanguard Research* are analogous to this case. The patentee had previously sued the plaintiff on non-patent claims (e.g., trade secret claims), but made "'repeated statements that it does not intend to sue Vanguard for patent infringement.'" *Vanguard Research*, 304 F.3d at 1254. The district court granted the patentee's motion to dismiss after it "found no actual controversy based on 'PEAT's repeated statement that it does not intend to sue Vanguard for patent infringement and its ongoing failure to bring such a suit.'" *Id.* at 1255. The Federal Circuit reversed, noting that the filing of the earlier lawsuit, though not involving the patents, and informing PEAT's customers that it was not licensed, showed "'a willingness to protect the technology'" (quoting from *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987)), and holding that "the appropriate inquiry asks whether Vanguard had a reasonable apprehension that PEAT would sue it for patent infringement *in the future* . . . . Filing a lawsuit for patent infringement would be just another logical step in its quest to protect its technology." *Id.* at 1255 (emphasis added). *See also Goodyear Tire & Rubber Co.*, 824 F.2d at 956 (holding that patentee's president's statement that he had not authorized the bringing of an infringement suit was irrelevant in light of circumstances giving rise to a reasonable apprehension that the patentee would bring suit in the future); *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1484 (Fed. Cir. 1998) (case or controversy is not destroyed by statement of a change of mind by patentee "disavowing" previous statements, because Declaratory Judgment Act was intended to forestall "scare-and-run tactics"). The question is not whether Columbia intends to file suit against Plaintiffs "right now." Columbia has insistently reserved its rights to sue Plaintiffs in the future regarding products Plaintiffs are *now* distributing,[10] and therefore a case and controversy exists *now* between the parties.

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[10] Columbia's counsel were even quoted in the press, following this Court's November 5

II. Columbia's alternative argument, that the Court should decline to exercise jurisdiction even if there is a case or controversy, lacks merit

The Federal Circuit's recent decision in *Capo, Inc. v. Dioptics Medical Products, Inc.*, 387 F.3d 1352 (Fed. Cir. 2004), demonstrates that courts should not decline to exercise jurisdiction over declaratory judgment actions merely because the patentee is not "right now" prepared to sue.

In *Capo,* the district court found that an actual controversy existed between the parties but declined to decide whether the plaintiff had a reasonable apprehension that the patentee would bring an infringement suit, deciding instead to exercise its discretion to dismiss the case because it was not "sufficiently crystallized." *Capo*, 387 F.3d at 1354. The Federal Circuit reversed, holding that the district court had abused its discretion and emphasizing the strict limits on courts' discretion to decline to exercise jurisdiction:

> There must be well-founded reasons for declining to entertain a declaratory judgment action. Absent such reasons, precedent establishes that when there has been no direct charge of infringement by the patentee, and an actual controversy exists due to ongoing activity that has been accused of infringement, the accused infringer has the right to resolve the dispute.

Id. at 1355. *See also id.*, at 1357 ("There must be a sound basis for refusing to adjudicate an actual controversy, for the policy of the Act is to enable resolution of active disputes"). After finding that the record demonstrated plaintiff's reasonable apprehension of suit (*id.* at 1356), the Federal Circuit explained why dismissal would be inappropriate:

> The refusal to exercise jurisdiction leaves Capo helpless and immobile so long as the patent owner refuses to grasp the nettle and sue. In patent cases the court's refusal to accept a declaratory action also raises issues of public interest, for patent rights are of competitive impact as well as innovation incentive. The present dispute has immediacy and reality, the criteria of Article III. Resolution of this dispute is within the court's

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ruling, to the effect that the "ruling leaves open the possibility of a future decision by the government agency that would extend the school's rights after all." Boston *Globe, Judge Halts Patent Suits Against Columbia* (Nov. 9, 2004), attached hereto as Exhibit F.

> capability, and it is the district court's responsibility to resolve it. Declining to do so is an abuse of discretion.

Id. at 1358 (internal quotations and citations omitted).

Similarly, in *Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672-73 (Fed. Cir. 1991), the court reversed dismissal of a declaratory judgment action where the patent was subject to an interference proceeding but the defendant was engaged in ongoing activity that might later be found to be infringement. The court found it to be an abuse of discretion not to hear the case in light of the potential harm to the plaintiff:

> As 3M continues to sell products it believes do not infringe, its potential liability grows. These are among the problems the Declaratory Judgment Act sought to alleviate.

Id. at 673. The court rejected the defendant's argument – like that made by Columbia here – that the pendency of proceedings in the PTO, which might moot the dispute, permit the court to decline jurisdiction. On the contrary, the court ruled "3M is entitled by the Declaratory Judgment Act to have a decision on the infringement question and not to have to wait until the interference is finally resolved." *Id.* at 674.[11]

III. Columbia's motion should in any event be denied as to Plaintiffs' Sixth Claim because a case or controversy exists regarding whether Columbia engaged in repressive practices under the License Agreement

Apart from Plaintiffs' reasonable apprehension that Columbia will sue them in the future for infringing the '275 patent, a case or controversy also exists regarding whether Columbia

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[11] The Federal Circuit has also recently stated that it is an abuse of discretion to dismiss a declaratory relief challenge to a patent even if the plaintiff has confidence that ultimately it will have no liability, because "there are other uncertainties, including whether there will be legal proceedings at all," and that threatened parties "are entitled to sue to bring an end to the threat, despite their confidence in their position." *Electronics for Imaging, Inc. v. Coyle*, --- F.3d ---, No. 04-1266 (Fed. Cir., Jan. 5, 2005), p. 8. The situation with regard to the issued '275 patent, which Columbia can later assert to claim damages because of current conduct of

violated the License Agreement by engaging in repressive practices. Columbia's motion entirely ignores that the Sixth Claim seeks a declaration of rights under the License Agreement – as do the Third and Fourth Causes of Action in Columbia's counterclaim against Amgen in the MDL proceeding – and thus does not depend on any threat by Columbia to sue for infringement.

Plaintiffs are express third party beneficiaries of the License Agreement (*see* Compl., Ex. D, §§ 1(a) and 2(a)), which incorporates by reference the same obligations imposed by the United States Government on Columbia pursuant to 35 U.S.C. §§ 200-211, regulations thereunder, and the determination letter to Columbia from the Department of Health and Human Services dated February 24, 1981. *See* Compl., ¶ 22, Ex. D at App. A. Among those obligations is an obligation imposed on Columbia by the determination letter and 45 C.F.R. § 8.2(b) to refrain from "unreasonable royalties and repressive practices," an obligation imposed on Columbia to avoid any unusual restrictions (45 C.F.R. § 8.0(c)), and an obligation imposed on Columbia to refrain from "unreasonable restrictions or excessive royalties" (45 C.F.R. § 8.1(b)) (collectively, the obligation to refrain from engaging in "repressive practices").

Columbia's entire pattern of conduct leading to and involving the Axel patents constituted repressive practices, including: improperly attempting to extend the terms of the Axel patents (Compl., at ¶¶ 25-28); delaying the prosecution leading to the '275 patent to obtain the '275 patent after the prior issued Axel patents had expired (*id.* at ¶¶ 29-31); making misrepresentations and misleading omissions that were material and non-cumulative to the examination and or patentability of the Axel patents and the '275 patents (*id.* at ¶¶ 32-74); and alleging that the Axel patent applications and the '275 patent cover Plaintiffs' activities (*id.* at ¶ 75). By engaging in these repressive practices, Columbia violated the License Agreement, and is

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Plaintiffs, is entirely different from the situation cited by Columbia where no patent was yet in

accordingly barred from enforcing the '275 patent and/or terminating the License Agreement. *Id.* at ¶¶ 104-105.

Columbia never explains why subject matter jurisdiction is lacking as to this claim. Columbia's motion to dismiss the parallel claim by Amgen was denied on the merits by the transferor court in the *Amgen* action, and Columbia never contested subject matter jurisdiction.

CONCLUSION

For the reasons set forth above, Columbia's motion to dismiss should be denied.

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Respectfully submitted,

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existence. *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479, 482 (Fed. Cir. 1996).